USP Chapter 797 Final Requirements

Because Practice Matters! to the AAAAI

Personnel Hygiene and Garbing*

All personnel who perform compounding procedures must follow specific hygiene and garbing requirements, including the following:

- Hand washing procedures as outlined below
- Minimum garbing requirements include:
  - Sterile powder-free gloves
  - Low-lint garment with sleeves that fit snugly around the wrists and that is enclosed at the neck
  - Face mask
  - Low-lint, disposable cover for shoes
  - Low-lint, disposable cover for head that covers the hair and ears and, if applicable, disposable cover for facial hair

Hand Hygiene Procedure

To appropriately wash hands before compounding, follow these steps:

1. Remove visible debris from underneath fingernails under warm running water using a disposable nail cleaner.
2. Wash hands and forearms up to the elbows with soap and water for at least 30 seconds.
3. Dry hands and forearms to the elbows completely with low-lint disposable towels or wipes.
4. Brushes must not be used for hand hygiene. Hand dryers must not be used. A closed system of soap (i.e. non-refillable container) to minimize the risk of extrinsic contamination must be readily available or in close proximity to the sink.
5. Apply an alcohol-based hand rub to dry skin, following the manufacturer's instructions for the volume of product to use.
6. Apply product to one hand and rub hands together, covering all surfaces of hands and fingers, until hands are dry.
7. Allow hands to dry thoroughly before donning sterile gloves.

Documentation

Compounding Records must include at least the following information:

- Name, concentration, volume, vendor or manufacturer, lot number, and expiration date for each component
- Date and time of preparation of the allergenic extract
- Assigned internal identification number
- Identity of all individuals involved in each step
- Total quantity compounded
- Assign Beyond Use Date (BUD) and storage requirements
- Results of Quality Control procedures (e.g. visual inspection, second verification of quantities)

* The order of garbing must be determined by the facility and documented in the facility's standard operating procedures

6/6/2019

Additional information is available in USP General Chapter <797> Pharmaceutical Compounding-Sterile Preparations.

If you have questions, contact advocacy@aaaai.org.

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Personnel Qualifications

Before beginning to independently prepare allergen extracts, all compounding personnel must complete training and be able to demonstrate knowledge of theoretical principles and skills for sterile compounding. Personnel must demonstrate proficiency in these procedures by passing written or electronic testing before being allowed to compound allergenic extract prescription sets.

- Successfully complete gloved fingertip and thumb sampling on both hands, no fewer than 3 separate times. After the initial competency evaluation, compounding personnel must successfully complete gloved fingertip and thumb sampling at least every 12 months.
- Successfully complete media fill test procedures every 12 months.
- Personnel who fail competency evaluations must successfully pass reevaluations in the deficient area(s) before they can resume compounding the allergenic extract prescription sets. The designated person(s) must identify the cause of failure and determine appropriate retraining requirements.
- Personnel who have not compounded an allergen extract prescription set in more than 6 months must be reevaluated with a written exam or electronic test, gloved fingertip and thumb sampling, and a media fill test before resuming compounding duties.

Gloved Fingertip and Thumb Sampling Procedure

Perform evaluation after completing hand hygiene and garbing procedures.

- Use one sampling device per hand (e.g., plates, paddles, or slides) containing general microbial growth agar [e.g., trypticase soy agar (TS)] supplemented with neutralizing additives (e.g. lecithin and polysorbate 80) as this agar supports both bacterial and fungal growth.
- Label each sampling device with a personnel identifier, whether it was from the right or left hand, and the date and time of sampling.
- Do not apply 70% isopropyl alcohol (IPA) to gloves immediately before touching the sampling device because this could cause a false-negative result.
- Using a separate sampling device for each hand, collect samples from all gloved fingers and thumbs from both hands by rolling finger pads and thumb pad over the agar surface.
- Incubate the sampling device at a temperature of 30° -35° for no less than 48 hours and then at 20° -25° for no less than 5 additional days. Store media devices during incubation to prevent condensate from dropping onto the agar and affecting the accuracy of the colony-forming units (cfu) reading (e.g., invert plates).
- Record the number of CFU per hand (left hand, right hand).
- Determine whether the CFU action level is exceeded by counting the total number of CFU on both hands.

Media-Fill Testing Procedure

- If all of the starting components are sterile to begin with, manipulate them in a manner that simulates sterile-to-sterile compounding activities, and transfer the sterile soybean-casein. Digest media into the same types of container-closure systems commonly used at the facility. Do not further dilute the media unless specified by the manufacturer.
- If some of the starting components are nonsterile to begin with, use a nonsterile soybean-casein digest powder to make a solution. Dissolve nonsterile commercially available soybean-casein medium in nonbacteriostatic water to make a 3% nonsterile solution. Manipulate it in a manner that simulates nonsterile-to-sterile compounding activities. Prepare at least 1 container as the positive control to demonstrate growth promotion, which is indicated by visible turbidity upon incubation.
- Once the compounding simulation is completed and the final containers are filled with the test media, incubate them in an incubator for 7 days at 20°–25° followed by 7 days at 30°–35° to detect a broad spectrum of microorganisms.
- Failure is indicated by visible turbidity or other visual manifestations of growth in the media in one or more container-closure units(s) on or before 14 days.

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